

**RECEIVED  
CENTRAL FAX CENTER****SEP 18 2006****REMARKS**

Favorable reconsideration of this application is respectfully requested. Claims 1, 10, 11, and 20 are amended. Claim 21 is added. No new matter has been added. Claims 1, 3, and 6-21 are pending.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claims 10 and 11 have been amended to replace the term "causing" with the term "allowing." Applicant respectfully submits that such revision clarifies that the fructosyl amino acid oxidase treatment follows the pretreatment of the hemolyzed sample. Thus, the claims are definite for at least the foregoing.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 3, and 6-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The rejection contends that the term "hemoglobin degradation product" is unclear and not clearly defined in the specification. Applicants respectfully disagree and contend that the term is readily understandable in the context of the present invention. Applicants respectfully submit that one of skill would recognize the term to refer to an enzymatically digested hemoglobin that is formed, for example by degradation of hemoglobin using a protease prior to the redox reaction. See for example page 12, lines 5-12 of the specification, which Applicants submit corresponds to such explanation. Moreover, the treatment described throughout Applicants' disclosure is consistent with such explanation. Therefore, claims 1, 3 and 6-20 are definite for at least these reasons.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ouyang et al. (U.S. Patent No. 5902731). Applicants respectfully traverse this rejection.

Claim 1 recites a method for measuring an analyte in a sample containing hemoglobin or a hemoglobin degradation product that includes among other features, that prior to the redox reaction, adding at least one of a selected group of sulfur-containing

compounds, or adding at least one of the selected sulfur-containing compounds and at least one of a selected group of nitrogen-containing compounds.

Ouyang et al. does not show or disclose claim 1. Ouyang et al. discloses a method for measuring ketone bodies in blood samples using a redox reaction. However, Ouyang et al. does not disclose adding at least one of a selected group of sulfur-containing compounds, or adding at least one of the selected sulfur-containing compounds and at least one of a selected group of nitrogen-containing compounds to a sample. In fact, Ouyang et al. merely discloses using nitrite salts. (Col. 5, lines 17-28.) Thus, the cited reference does not disclose adding at least a sulfur-containing compound or adding a combination of a sulfur-containing compound with a nitrogen containing compound. Ouyang et al. does not anticipate claim 1.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 3, and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouyang et al. (above) in view of Komori et al. (U.S. Patent Application Publication No. US 2002/0025546).

Claim 1 has been discussed. As with claim 1, claim 20 includes, that prior to the redox reaction, adding at least one of a selected group of sulfur-containing compounds or adding at least one of the selected sulfur-containing compounds and at least one of a selected group of nitrogen-containing compounds. Claim 20 recites a different set of sulfur-containing compounds than claim 1 by also including sodium lauryl sulfate in a method for measuring a glycated protein in a sample containing hemoglobin or a hemoglobin degradation product. Claims 1 and 20 can provide advantages such that the influence of hemoglobin or its degradation product can be prevented without affecting the measurement system. (See for example page 3, lines 12-18 and Examples of Applicants' disclosure). As a result, more accurate determinations can be conducted that are useful for various clinical medicine testing. (*Id.*)

The cited references do not render the claimed invention obvious. Ouyang et al. has been distinguished above for not disclosing adding at least a sulfur-containing compound required by claim 1. Likewise, Ouyang et al. does not disclose the features required by claim 20, namely the feature of adding at least a sulfur-containing compound.

Komori et al. does not provide what is missing from Ouyang et al. Komori et al. does not teach or suggest any of the sulfur-containing compounds or the nitrogen-containing compounds recited in claims 1 and 20. In fact, Komori et al. merely mentions adding a nitro compound and particularly 2-(4-iodophenyl)-3-(2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H-tetrazolium salt. However, Komori et al. discloses nothing on adding at least a sulfur-containing compound. Furthermore, the nitrogen compound mentioned in Komori et al. do not satisfy the nitrogen-containing compounds recited in claims 1 and 20. Thus, Komori et al. does not remedy the deficiencies of Ouyang et al. for at least these reasons. Claims 1 and 20 are not obvious over Ouyang et al. and Komori et al.

Moreover, there is no suggestion or motivation in Ouyang et al. and Komori et al. to arrive at claims 1 and 20. The rejection contends that one of ordinary skill in the art would have been motivated to add a sulfur-containing compound and a nitrogen-containing compound singly and in conjunction. Applicants respectfully disagree. As noted in the Office Action, neither reference discloses adding at least sulfur-containing compounds or adding both sulfur and nitrogen-containing compounds. In fact, the references merely discuss using nitrogen compounds. Furthermore, the references do not disclose the particular compounds recited by the claimed invention. For at least these reasons, Applicants respectfully submit that the references do not provide any motivation or suggestion to arrive at claims 1 and 20 as amended. Claims 1 and 20 are not obvious.

For at least the foregoing, Applicants respectfully submit that claims 1 and 20 and the dependent claims are patentable over Ouyang et al. and Komori et al. taken together or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

With regard to added claim 21, Applicants respectfully submit that this claim is allowable over the references cited. Claim 21 is directed to a method for measuring an analyte in a sample containing hemoglobin or a hemoglobin degradation product using a redox reaction. Claim 21 includes, among other features, that prior to the redox reaction, adding at least one of a sulfur-containing compound-selected from the group consisting of dodecylbenzenesulfonic acid sodium salt, lithium lauryl sulfate, 4-aminoazobenzene-4'-sulfonic acid sodium salt, 4-amino-4'-nitrostilbene-2-2'-disulfonic acid disodium salt, and

SEP 18 2006

4,4'-diazidostilbene-2,2'-disulfonic acid disodium salt, or at least one of a nitrogen-containing compound selected from the group consisting of 2,4-dinitrophenol, p-nitrophenol, 2,4-dinitroaniline, p-nitroaniline, 4-amino-4'-nitrostilbene-2,2'-disulfonic acid disodium salt, and nitrobenzene to the sample. In particular, claim 21 does not include sodium nitrite or potassium nitrite in the list of selected nitrogen-containing compounds. Ouyang et al. and Komori et al. do not teach or suggest adding the selected compounds recited by claim 21. For example, Ouyang et al. merely discloses nitrite salts such as sodium nitrite and potassium nitrite. However, these compounds do not satisfy claim 21. Therefore, claim 21 is allowable for at least these reasons.

With the above amendments and remarks, Applicants believe that the pending claims are in a condition for allowance. Favorable consideration in the form of a Notice of Allowance is respectfully requested. If any further questions arise, the Examiner is invited to contact Applicants' representative at the number listed below.



Dated: September 18, 2006

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER &  
LARSON, P.C.  
P.O. Box 2902-0902  
Minneapolis, MN 55402-0902  
(612) 455-3800

By: 

Douglas P. Mueller  
Reg. No. 30,300  
DPM/baw